

Applicant : Bruce D. Gaynor, et al.  
Serial No. : 08/833,838  
Filed : April 10, 1997  
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72. (Amended) The method according to Claim 71 wherein said peptide is 5-15 amino acids in length.

73. (Amended) The method according to Claim 71 wherein said peptide is 5-10 amino acids in length.

74. (Amended) The method according to Claim 71 wherein said peptide consists of d-Asp-Trp-Glu-Tyr-Ser.

Remarks

Claims 54-74 were pending in the above-identified application. With this Reply and Amendment, claims 59-70 are cancelled without prejudice or disclaimer and claims 54-58 and 71-74 are amended to more particularly point out and distinctly claim the invention.

Rejection Under 35 U.S.C. § 112, 1<sup>st</sup> Paragraph

All pending claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. It is asserted that undue experimentation would be required to practice the invention presented in the examined claims. The assertion of undue experimentation is based on the breadth of peptides claimed to treat glomerulonephritis, both in regard to the numbers of sequences covered by the peptides and that L and D forms of the peptides are covered. Applicants respectfully request reconsideration and withdrawal of this rejection in light of the claim amendments and the following remarks.

Applicants have amended the claims to cover only the D forms of the peptides, and only those few sequences covered by the consensus sequence established in the Experimental Details Section as shown to prevent glomerulonephritis.

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Glomerulonephritis is defined in the specification at page 11, line 29-page 12, line 1, as being caused by the deposit of antibodies to dsDNA in the glomeruli of renal tissue in kidneys. Derivation of the consensus sequence X1-Trp-X1-Tyr-X2, where X1 represents Asp or Glu, and X2 represents Gly or Ser, is discussed in the specification at page 16, lines 19-20, and Table 2.

Since the instant application establishes that a D-peptide sequence within the claimed consensus sequence inhibits deposition of dsDNA antibodies in the glomeruli of renal tissue *in vivo*, and since the skilled artisan would understand that any of the D forms within the consensus sequence would likely also inhibit such deposition, applicants assert that the claims as amended are enabled.

### Conclusion

Based on the claim amendments and the above discussion, applicants respectfully request passage of the amended claims to allowance. If there are any minor matters preventing such allowance, applicants request that Examiner Ewolt contact the undersigned attorney.

Respectfully submitted,

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Appendix A - Marked-Up Claims as Amended  
U.S. Patent Application No. 08/833,838  
Additions are underlined and deletions are bracketed

54. A method for treating glomerulonephritis mediated by anti-double stranded (ds)-DNA antibodies in a subject in need of such treatment comprising administering to said subject at least one peptide which binds an anti-double stranded DNA antibody in an amount effective to treat glomerulonephritis, wherein said peptide comprises a D- [an]amino acid sequence of [(i) X-Gly-Trp-X-Arg-Val (SEQ ID NO:3), wherein X represents any amino acid known in the art; (ii) X-Trp-X-Tyr-His-X (SEQ ID NO:4), wherein X represents any amino acid known in the art; (iii)] X1-Trp-X1-Tyr-X2 [(SEQ ID NO:2)], wherein X1 represents Asp or Glu, and X2 represents Gly or Ser[; or (iv) X1-Gly-X1-Trp-Pro-Arg (SEQ ID NO:5), wherein X1 represents Asp or Glu].

55. The method according to Claim 54 wherein said peptide is 5-30 D-amino acids in length[ and comprises X-Gly-Trp-X-Arg-Val (SEQ ID NO:3), wherein X represents any amino acid known in the art].

56. The method according to Claim 54 wherein said peptide is 5-15 D-amino acids in length[ and comprises X-Gly-Trp-X-Arg-Val (SEQ ID NO:3), wherein X represents any amino acid known in the art].

57. The method according to Claim 54 wherein said peptide is 5-10 D-amino acids in length[ and comprises X-Gly-Trp-X-Arg-Val (SEQ ID NO:3), wherein X represents any amino acid known in the art].

58. The method according to Claim 54 wherein said peptide is 5 D-amino acids in length[consists of X-Gly-Trp-X-Arg-Val (SEQ ID NO:3), wherein X represents any amino acid known in the art].

71. The method according to Claim 54 wherein said peptide is 5-30 amino acids in length and comprises d-Asp-Trp-Glu-Tyr-Ser[ (SEQ ID NO:2)].

72. The method according to Claim [54]71 wherein said peptide is 5-15 amino acids in length[ and comprises d-Asp-Trp-Glu-Tyr-Ser (SEQ ID NO:2)].

73. The method according to Claim [54]71 wherein said peptide is 5-10 amino acids in length[ and comprises d-Asp-Trp-Glu-Tyr-Ser (SEQ ID NO:2)].

74. The method according to Claim [54]71 wherein said peptide consists of d-Asp-Trp-Glu-Tyr-Ser[ (SEQ ID NO:2)].